

by Norzel's Beauty Products Manufacturing Co., Inc.; and charging misbranding in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article showed that it consisted essentially of water, isopropyl alcohol, glycerin, and small proportions of sodium chloride, potassium iodide, sodium carbonate, iodoform, and perfume material. Bacteriological tests showed that it was not an antiseptic under conditions of practical usage.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading since the article would not accomplish the effects claimed: (Label) "Antiseptic * * * use I. G. freely around cuticles to prevent infections. * * * Use I. G. after shaving to prevent barbers itch and many other infections"; (circular) "First Aid Antiseptic The Sign of Protection Against Irritation and Infection * * * The danger of permanent wave burn lies not so much in the burn itself as in the infection which may arise. Burns and infection do not always make themselves apparent before the client leaves your shop. To be on the safe side always take the sure, easy precaution of sponging the scalp with I G after permanent waving * * * A simple cut caused by a hangnail or cuticle being removed by nippers or scissors may leave the cuticle open to incipient infection. Infection may take hours or days before it becomes noticeable. To serve the best interests of your clients and to protect your own business, use I G freely around the cuticle after each manicure. The healing action of I G soothes the hurt and its germicidal action sterilizes the wound. Infection is arrested before it even starts! * * * Falling hair * * * and excessive dandruff are frequently due to germs. The germicidal action of I G * * * will prevent causative germs from setting in when pores are open. * * * I G will prevent the danger of any unpleasant after effects. * * * Many of your customers are sensitive to the effects of hair dyes. The dye enters the pores of the scalp and an itching sensation is noticed. If the affected person does not aggravate this itching the effects will be negligible. Scratching or rubbing may cause serious infection which will reflect on you. To prevent unpleasant 'kick-backs' moisten absorbent cotton and apply to the treated areas. I G enters the pores and breaks down the dye. The cause of itching is removed and no after effects are noticed. I G will soothe irritation and prevent infection. * * * After each eyebrow treatment sponge the surrounding area with I G and take precaution against infection. Protect yourself against these dangers. —and what precautions do you take in your business to protect your patrons from infections? If you have been a constant user of I G this question can be answered convincingly. The slight extra care you take in applying I G as a preventative measure is well repaid by the freedom you find from worry, * * * Before being placed on the market I G was exhaustively tested on every point of effectiveness * * * Today I G is available to you and you can use it with every confidence in its ability to protect your clientele."

The article was alleged to be misbranded further in that certain statements in the labeling regarding its curative and therapeutic effects, falsely and fraudulently represented that it would prevent, heal, and eliminate infections, would take away inflammation; that it was effective as an antiseptic scalp treatment to arrest hair falling and to remove dandruff; that it would restore cells and pores to a normal healthy condition; and that it was effective as a preventative of barber's itch and as a treatment for burns and skin eruptions.

Misbranding was alleged further in that the package failed to bear on its label a statement of the quantity or proportion of isopropyl alcohol contained in the article since no declaration of the quantity or proportion of isopropyl alcohol was made.

On May 2, 1938, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

M. L. WILSON, *Acting Secretary of Agriculture.*

29003. Adulteration of catgut ligatures. U. S. v. 1,000 Dozen Tubes of Catgut Ligatures. Unsterile portion condemned and destroyed. Remainder, with consent of claimant, retained by marshal and subsequently ordered destroyed. (F. & D. No. 29736. Sample No. 28829-A.)

This product consisted of ligatures identified by various control numbers. Ligatures were examined from four of the control numbers. Nine out of twenty-four examined from one of the control numbers were unsterile.

On January 10, 1933, the United States attorney for the District of Columbia, acting upon a report by the Secretary of Agriculture, filed in the Supreme Court

of the District of Columbia, holding a district court, a libel praying seizure and condemnation of 1,000 dozen tubes of catgut ligatures at Washington, D. C.; alleging that the article had been shipped in interstate commerce on various dates between June 22, 1931, and September 14, 1932, from Boston, Mass., by Jaeger-Bigelow Co.; and charging adulteration in violation of the Food and Drugs Act.

The article was alleged to be adulterated in that its purity fell below the professed standard or quality under which it was sold.

On June 29, 1933, F. W. Jaeger, having appeared as claimant, a demurrer and exceptions to the libel were filed upon the grounds that catgut ligatures were not within the purview of the Food and Drugs Act; that the plaintiff had not complied with the provisions of the Food and Drugs Act, section 11, pertaining to notice and hearing; and that the libel was indefinite, ambiguous, and uncertain in that it did not appear in what respect the ligatures were adulterated within the meaning and intent of the Food and Drugs Act.

On October 27, 1933, the court handed down the following opinion:

ADKINS, *Justice*: "(1) The principal question in this case is whether the catgut ligatures come within the definition of a drug as set forth in the Pure Food and Drugs Act.

"The term 'drug' as used in that act is defined to include 'all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.'

"Catgut ligatures are not recognized in either the United States Pharmacopoeia or National Formulary. Do they come within the remaining part of the definition?

"Catgut ligatures are a substance. They are in fact used by physicians in stitching together parts of the body after operations. Such operations are frequently for the purpose of curing disease. I am unable to escape the conclusion that these ligatures come strictly within the second part of the definition.

"(2) I think a notice and hearing under section 11 of the Food and Drugs Act is not a condition precedent to the jurisdiction of the court. *U. S. v. Rawleigh Co.*, 57 Fed. (2d) 505. *U. S. v. Morgan*, 222 U. S. 274. Therefore the first and second grounds of exception are overruled.

"(3) The statute provides that a drug shall be deemed adulterated—

"Second. If its strength or purity fall below the professed standard or quality under which it is sold."

"The charge in the libel is in the above language. I think this is not a sufficient allegation, and that the third exception should be sustained.

"Plaintiff relies upon the rule that a purely statutory offense may be alleged in the words of the statute.

"This is not a criminal proceeding; if it were I doubt if the rule would be applicable under the facts of this case.

"In my judgment the owner of the property seized is entitled to have the libel state the professed standard or quality under which the ligatures were sold and the respects in which their strength or purity fell below that standard or quality.

"The third ground of exception will be sustained, with leave to amend."

On February 14, 1934, an amended libel was filed, alleging that the article was adulterated in that its purity fell below the professed standard of quality under which it was sold, since it was sold under United States Government Master Specification No. 357, pertaining to ligatures, which specification provides that each strand of catgut ligatures shall be sterile; whereas a considerable number of ligatures delivered, which were the subject matter of the proceeding, were not sterile, that is to say, on such ligatures there were present viable aerobic spore-forming organisms.

On March 16, 1934, the claimant filed an answer to the amended libel. No further proceedings having been had and the claimant having consented thereto, on April 25, 1938, the court entered judgment of condemnation against the ligatures which had been found to be unsterile, i. e., one control number, and they were ordered destroyed. Owing to the lapse of time and the perishable nature of the product, the remainder was ordered retained in the custody of the United States for such action as the court might deem appropriate, and on May 12, 1938, it was likewise ordered destroyed.

M. L. WILSON, *Acting Secretary of Agriculture.*